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Northern District of California

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA

STEVEN BRUCE,

Plaintiff,

v.

ALEX M. AZAR, et al.,

Defendants.

Case No. 18-cv-05022-HSG

ORDER GRANTING MOTIONS TO IISS AND ADMINISTRATIVE ON TO FILE UNDER SEAL, AND DENYING MOTIONS TO SUPPLEMENT THE RECORD

Re: Dkt. Nos. 24, 36, 39, 40, 64, 70

Pending before the Court are three motions to dismiss, filed separately by Defendant California Physicians' Service d/b/a Blue Shield of California ("Blue Shield"), Dkt. No. 36; Defendant Envision Insurance Company ("Envision"), Dkt. No. 40; and Defendant Alex M. Azar II, Secretary of the United States Department of Health and Human Services ("DHHS"), Dkt. No. 39. DHHS also filed a motion to file the administrative record under seal, Dkt. No. 64, and Plaintiff Steven Bruce filed two motions to supplement the administrative record, Dkt. Nos. 24, 70. For the reasons articulated below, the Court **GRANTS** the motions to dismiss without leave to amend. The Court also **GRANTS** DHHS's motion to file the administrative record under seal, and **DENIES** Plaintiff's motions to supplement the administrative record.

I. **BACKGROUND**

Plaintiff brought this action against Defendants on August 16, 2018, seeking judicial review of the final decision by the Medicare Appeals Council ("MAC") denying Plaintiff coverage for the drug Serostim. Dkt. No. 1. Plaintiff is a Medicare beneficiary enrolled in the Part D prescription drug plan, administered by Envision in 2016 and Blue Shield in 2017. Dkt. No. 19 ("FAC") ¶¶ 1, 11, 23. In early 2016, Plaintiff was diagnosed with lipodystrophy, an auto-immune disease, and wasting syndrome. *Id.* ¶ 12. To treat his conditions, his primary care physician

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prescribed the drug Serostim. *Id.* ¶ 13. Both Envision and Blue Shield denied coverage for Serostim in 2016 and 2017, respectively, because Serostim was not prescribed to Plaintiff for a use approved by the Food and Drug Administration ("FDA") or supported by a Medicare-approved drug compendium. Id. ¶¶ 14, 24.

Plaintiff appealed both Envision and Blue Shield's denials of coverage. Id. ¶ 15–21, 25– 30. The appeals went through timely reconsideration requests with the Independent Review Entity and hearings in front of Administrative Law Judges ("ALJs") Myles and Gulin. Id. Both ALJs denied coverage, and Plaintiff appealed those decisions to the MAC. Id. ¶¶ 17–21, 27–30. The MAC related and consolidated both appeals and issued a final decision on July 12, 2018, denying coverage of Serostim. Id. ¶ 30.

Plaintiff now brings this action against his insurers, Blue Shield and Envision, and DHHS, to "appeal a final decision of the DHHS that denied coverage for Serostim." *Id.* ¶ 8. In the FAC, Plaintiff alleges the following four claims against Defendants: (1) "Defendants' decisions denying Plaintiff's claim for Medicare coverage of Serostim is [sic] not supported by substantial evidence and is [sic] incorrect as a matter of law," id. ¶ 35; (2) Defendants violated Plaintiff's due process rights "by refusing to provide coverage," id. ¶¶ 36–41; (3) Defendants, "[b]y providing coverage for Serostim only to individuals who have HIV," denied Plaintiff benefits in violation of Section 504 of the Rehabilitation Act of 1973, id. ¶¶ 42–51; and (4) Defendants Envision and Blue Shield, in refusing to provide coverage, discriminated against Plaintiff due to "his HIV-negative status," in violation of Title III of the Americans with Disabilities Act, id. ¶¶ 52–55.¹ Plaintiff requests that the Court reverse the decision of the agency and award Plaintiff benefits, along with any outof-pocket costs and attorneys' fees and expenses. Id., Prayer for Relief.

II. **MOTIONS TO DISMISS**

Defendants Envision and Blue Shield move to dismiss the complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. Dkt. Nos. 36, 40. Specifically, Envision and

Plaintiff voluntarily withdrew his Title III claim against Defendants Envision and Blue Shield, see Dkt. No. 48 at 7; Dkt. No. 49 at 6, and the Court therefore **GRANTS** Defendants' motions to dismiss Plaintiff's fourth cause of action.

Blue Shield assert that they are not the proper defendants in this action, and even if they are, Plaintiff has not alleged sufficient facts to state a claim upon which relief can be granted. *Id*. DHHS moves to dismiss Plaintiff's second and third causes of action for lack of subject matter jurisdiction under Rule 12(b)(1), and, alternatively, for failure to state a claim under Rule 12(b)(6). Dkt. No. 39.

A. Legal Standards

i. Rule 12(b)(1)

A defendant may move for dismissal on grounds that the court lacks subject matter jurisdiction over the action. Fed. R. Civ. P. 12(b)(1). Federal district courts are courts of limited jurisdiction, and "[n]o principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 341 (2006) (quotations omitted). It is the plaintiff's burden to establish subject matter jurisdiction. *See Ass'n of Am. Med. Colls. v. U.S.*, 217 F.3d 770, 778-79 (9th Cir. 2000); *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 376-78 (1994). "A Rule 12(b)(1) jurisdictional attack may be facial or factual." *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004) (citing *White v. Lee*, 227 F.3d 1214, 1242 (9th Cir. 2000)). A facial attack "asserts that the allegations contained in a complaint are insufficient on their face to invoke federal jurisdiction." *Id.* A factual attack "disputes the truth of the allegations that, by themselves, would otherwise invoke federal jurisdiction." *Id.*

ii. Rule 12(b)(6)

Federal Rule of Civil Procedure 8(a) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A defendant may move to dismiss a complaint for failing to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6). "Dismissal under Rule 12(b)(6) is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory." *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th Cir. 2008). To survive a Rule 12(b)(6) motion, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

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A claim is facially plausible when a plaintiff pleads "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

In reviewing the plausibility of a complaint, courts "accept factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." Manzarek v. St. Paul Fire & Marine Ins. Co., 519 F.3d 1025, 1031 (9th Cir. 2008). Nonetheless, Courts do not "accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." In re Gilead Scis. Sec. Litig., 536 F.3d 1049, 1055 (9th Cir. 2008).

If dismissal is appropriate under Rule 12(b)(6), a court "should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." Lopez v. Smith, 203 F.3d 1122, 1130 (9th Cir. 2000) (quotations and citation omitted).

B. Discussion

i. Envision and Blue Shield Are Not Proper Defendants

Plaintiff's first cause of action against Envision and Blue Shield is an administrative challenge to "Defendants' decisions denying Plaintiff's claim for Medicare coverage of Serostim." FAC ¶¶ 34–35. Blue Shield and Envision maintain that they are not proper defendants for such a claim, because under the statutory review process, the only proper defendant in an appeal of the agency's decision is the Secretary of DHHS. Dkt. No. 36 at 3–4; Dkt. No. 40 at 3.

Under Section 1852 of the Social Security Act, codified in 42 U.S.C. § 1395 and the related sections, a Medicare beneficiary may obtain judicial review of the MAC's final decision pursuant to 42 U.S.C. § 405(g). See 42 U.S.C. § 1395w-104(h). The governing regulations specify that a Part D beneficiary may obtain court review of the MAC's decision if the amount in

² Section 1395w-104(h) provides for judicial review of appeals Part D beneficiaries bring. 42 U.S.C. § 1395w-104(h). Although § 405(g) is not expressly listed in that section, § 1395w-104(h) incorporates Part C's judicial review provision, § 1395w-22(g), which in turn provides for judicial review under § 405(g). See id.; see also Do Sung Uhm v. Humana, Inc., 620 F.3d 1134, 1140 n.9 (9th Cir. 2010).

controversy meets the threshold requirement estimated annually by the Secretary of DHHS. 42 C.F.R. § 423.2136(a). In such a review, the "Secretary of HHS, in his or her official capacity, is the proper defendant." *Id.* § 423.2136(d)(1).

Plaintiff's first cause of action seeks review of the final decision of the MAC. See FAC ¶¶ 34–35. By the plain language of 42 C.F.R. § 423.2136(d)(1), DHHS is the only proper defendant for such a claim, and therefore Blue Shield and Envision are not proper defendants. See Madsen v. Kaiser Found. Health Plan, Inc., No. 08CV2236-WQH-JMA, 2009 WL 1537878, at *4 (S.D. Cal. June 2, 2009). As to Plaintiff's two remaining claims, because they are derivative of his claim challenging the MAC's final decision, those too must be dismissed. See FAC, Prayer for Relief ¶ 1 (Plaintiff requests the Court "[r]everse and set aside the decision of the DHHS and award such benefits as to which Plaintiff is entitled"); see also id. ¶¶ 1 ("This complaint is for judicial review of a final decision of the Department of Health and Human Services"), 41 (second claim alleging that "Defendants Envision and Blue Shield violated Plaintiff's due process rights under the Fifth Amendment [] by refusing to provide coverage"), 48 (third claim alleging that Envision and Blue shield, "[b]y providing coverage for Serostim only to individuals who have HIV," denied Plaintiff the opportunity to receive benefits). ³

The Court therefore **DISMISSES** Plaintiff's action against Defendants Envision and Blue Shield without leave to amend.

ii. With Respect to DHHS, the Court Does Not Have Subject Matter Jurisdiction Over the Second and Third Causes of Action

DHHS does not seek to dismiss Plaintiff's first cause of action in its motion, but only moves to dismiss Plaintiff's second and third causes of action on the basis that the Court, under 42 U.S.C. § 405(h), does not have subject matter jurisdiction over those claims. Dkt. No. 39 at 5, 7. As discussed earlier, a beneficiary may obtain judicial review of the agency's decision through § 405(g). Section 405(h), a related provision, "channels most, if not all, Medicare claims through

³ Because the Court finds that Envision and Blue Shield are not proper defendants in an administrative challenge and the remaining claims are derivative, the Court need not reach the merits of Defendants' arguments that the second and third causes of action independently fail to state cognizable claims. *See* Dkt. No. 36 at 5–9; Dkt. No. 3–5.

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this special review system." Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 8 (2000); see also Do Sung Uhm, 620 F.3d at 1140 (Section 405(g) is the "sole avenue for judicial review for claims arising under the Medicare Act") (quoting Heckler v. Ringer, 466 U.S. 602, 614–15 (1984)) (quotations omitted). Specifically, § 405(h) states that:

> The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h) (emphasis added). DHHS contends that the statutory language "arising under" includes any action derivative of a denial of benefits review, including Plaintiff's second and third claims, thereby barring judicial review of those claims. Dkt. No. 39 at 8.

The Supreme Court's holding in *Shalala* is dispositive. There, plaintiffs sued DHHS, asserting that certain Medicare-related regulations violated their statutory and constitutional rights. Shalala, 529 U.S. at 5–7. The Shalala Court held that plaintiffs' anticipatory challenge to the lawfulness of the regulations was precluded from judicial review under § 405(h). Id. at 25. In so holding, the Supreme Court reasoned that the language of § 405(h) "purports to make exclusive the judicial review method set forth in § 405(g)." Id. 10. Exclusive § 405(g) review applies to any claims "arising under" the Medicare Act, and "clearly appl[ies]" in a "typical [] Medicare benefits case, where an individual seeks a monetary benefit from the agency[,] the agency denies the benefit, and the individual challenges the lawfulness of that denial[,] irrespective of whether the individual challenges the agency's denial on evidentiary, rule-related, statutory, constitutional, or other legal grounds." Id.

This case falls squarely within the "typical [] Medicare benefits case" the Shalala Court described as not subject to judicial review. See id. Plaintiff's entire action rests on the premise that the agency's decision denying coverage of Serostim was unlawful. See FAC ¶¶ 38–40, 48, 50. Thus, "irrespective" of whether Plaintiff is attempting to challenge this denial on "statutory, constitutional or other legal grounds," the statute "plainly bars" judicial review of Plaintiff's

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second and third claims. See Shalala, 529 U.S. at 10.

Plaintiff argues that his claims are "not essentially a claim for benefits," but rather a challenge to an "arbitrary classification" that denies him "meaningful access" to Serostim. Dkt. No. 47 at 2–3. According to Plaintiff, his claims are related to "plan design [to save money], not to a precise level of care." Id. But Plaintiff does not coherently articulate what significance this purported distinction has, and the Supreme Court has found similar arguments unpersuasive. Section 405(h) applies where "both the standing and substantive basis for the presentation of a claim is the Medicare Act," regardless of whether the nature of the challenge is "collateral versus noncollateral." See Shalala, 529 U.S. at 12, 14. The Supreme Court has made clear that:

> [c]laims for money, claims for other benefits, claims of program eligibility, and claims that contest a sanction or remedy may all similarly rest upon individual fact-related circumstances, may all similarly dispute agency policy determinations, or may all similarly involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions. There is no reason to distinguish among them in terms of the language or in terms of the purposes of § 405(h).

Id. at 14. See also Heckler, 466 U.S. at 614–16 (Section 405(h) bars jurisdiction over case involving challenge to agency's procedures); Weinberger v. Salfi, 422 U.S. 749 (1975) (no jurisdiction under § 405(h) even in case where plaintiffs did not request payment of benefits, but rather challenged agency's procedures and sought declaratory relief); Marin v. HEW, Health Care Fin. Agency, 769 F.2d 590, 592 (9th Cir. 1985) (Section 405(h) bars health care providers' claims for reimbursement under the Medicare Act even where claims were brought under the Federal Tort Claims Act for damages "caused by negligent failure," as such claims still "arise under" the Medicare Act). As in those cases, Plaintiff cannot circumvent the bar of § 405(h) by "imbu[ing]" his claims with federal question jurisdiction, as that "would render meaningless the jurisdiction restriction of § 405(h)." See Marin, 769 F.2d at 592. Section 405(g) thus provides the proper avenue for resolution of Plaintiff's claims. See Davis v. Astrue, 513 F. Supp. 2d 1137, 1145 (N.D. Cal. 2007) ("In sum, this court cannot assume jurisdiction based on Section 1331 over plaintiff's causes of action under the Rehabilitation Act and Due Process Clause").

Plaintiff's reliance on J.L. v. Soc. Sec. Admin., 971 F.2d 260 (9th Cir. 1992) and Am.

Council of the Blind v. Astrue, No. C 05-04696 WHA, 2008 WL 1858928 (N.D. Cal. Apr. 23, 2008) is unavailing. See Dkt. No. 51 at 7. J.L. predates Shalala and its holding has since been questioned in light of Shalala.⁴ And American Council of the Blind is fundamentally distinguishable from this action. The court in American Council found that plaintiffs' claims were not tied to any benefits. 2008 WL 1858928, at *5. Instead, those claims were premised on the agency's failure to communicate with plaintiffs in an accessible format, thereby depriving plaintiffs of "adequate notice and an opportunity to be heard." Id. at *1. Because the plaintiffs were challenging the agency's procedures for communicating with participants, and not the procedures for determining benefits, the court held the plaintiffs' claims did not arise under the Social Security Act and the court therefore had jurisdiction. Id. at *5. In contrast, there is no question that what Plaintiff is challenging here is clearly tied to his benefits.

Since the determination that it lacks jurisdiction over Plaintiff's second and third claims is dispositive, the Court need not address DHHS's alternative argument that the claims should be dismissed under Rule 12(b)(6). *See* Dkt. No. 39 at 9–16. Plaintiff's second and third causes of action are **DISMISSED** without leave to amend.

III. MOTIONS TO SUPPLEMENT THE ADMINISTRATIVE RECORD⁵

On October 25, 2018, Plaintiff filed a motion to supplement the administrative record ("AR"), alleging that the AR did not include the FDA label for Serostim and the American-Hospital Formulary Service Drug Information ("AHFS-DI") compendium for Serostim. Dkt. No. 24 at 2. DHHS opposed the motion as premature and subsequently lodged the administrative

⁴ The court in *Davis* stated that *J.L.* appears "inconsistent with the Supreme Court's subsequent holding in [*Shalala*] that legal challenges to agency practices and procedures are subject to the limitations in Section 405(h)." *Davis*, 513 F. Supp. 2d at 1144.

⁵ Although Plaintiff moves to "supplement" the record, based on a review of his pleadings, it

⁵ Although Plaintiff moves to "supplement" the record, based on a review of his pleadings, it appears Plaintiff is seeking to compel DHHS to "complete" the record. *See* Dkt. No. 70 at 4 (alleging that the agency considered and relied on the documents and should have included them in the AR); Dkt. No. 79 at 2 ("The materials and information at issue here is [sic] not extra-record evidence."). "Supplementing" and "completing" the AR are two distinct concepts: "completing the record" refers to including "materials which were actually considered by the agency, yet omitted from the administrative record," whereas "supplementing the record" refers to including "materials which were not considered by the agency, but which are necessary for the court to conduct a substantial inquiry." *Ctr. for Native Ecosystems v. Salazar*, 711 F. Supp. 2d 1267, 1274 (D. Colo. 2010). The Court will construe Plaintiff's motion as a motion to complete or, in the alternative, to supplement the AR, and apply both applicable standards.

record with the Court on February 5, 2019, including the FDA label for Serostim. Dkt. No. 34 at 3–4; Dkt. No. 61; Dkt. No. 64 (AR). While DHHS had agreed to supplement the AR with the AHFS-DI compendium for Serostim, DHHS avers that the compendium did not contain Serostim, so it did not include it. Dkt. No. 64-6 ¶ 2. Nonetheless, Plaintiff, in a statement to the court on February 6, 2019, affirmed that he still sought inclusion of the AHFS-DI compendium for Serostim. Dkt. No. 65. He also alleged that DHHS is compelled to provide two additional documents that were not identified before the Court in Plaintiff's initial motion: (1) the AHFS-DI compendium for "somatotropin," which Plaintiff posits is the generic compound of Serostim, and (2) the introductory portions of the AHFS-DI compendium. Dkt. No. 65.

Because the scope of Plaintiff's original motion had changed considerably, the Court directed Plaintiff to file a new motion, addressing the most current documents at issue. Dkt. No. 69. Plaintiff filed his second motion to supplement the administrative record on February 20, 2019.⁶ Dkt. No. 70. In the most recent motion, Plaintiff seeks to compel DHHS to complete, or supplement, the AR with the AHFS-DI compendia for Serostim and somatotropin, and the introductory portion of the AHFS-DI compendium, for the years 2016–2018.⁷ *Id.* at 2.

A. Legal Standard

Judicial review of an agency decision is limited to "the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). The administrative record is "not necessarily those documents that the agency has compiled and submitted as 'the' administrative record." *Thompson v. U.S. Dept. of Labor*, 885 F.2d 551, 555 (9th Cir. 1989) (citation omitted). Instead, it must be "the whole record," which "includes everything that was before the agency pertaining to the merits of its decision." *Portland Audubon Soc'y v. Endangered Species Comm.*, 984 F.2d 1534, 1548 (9th Cir. 1993) (citation omitted). The "whole record" thus encompasses "all documents and materials directly or

⁶ Since the most recent motion to supplement the administrative record supersedes Plaintiff's original motion, the Court **DENIES AS MOOT** the original motion, Dkt. No. 24.

⁷ In his reply, Plaintiff seeks documents for the years 2015–2019. Dkt. No. 79 at 2. Because the years 2015 and 2019 were not raised in his motion, the Court will not consider his request to complete the AR with documents from those years. *See* Dkt. No. 70.

indirectly considered by agency decision-makers and includes evidence contrary to the agency's position." *Thompson*, 885 F.3d at 555 (citation omitted).

The administrative record before the agency, however, does not include "every scrap of paper that could or might have been created." *Pinnacle Armor, Inc. v. United States*, 923 F. Supp. 2d 1226, 1237 (E.D. Cal. 2013) (quoting *TOMAC v. Norton*, 193 F. Supp. 2d 182, 195 (D.D.C. 2002)). Also, an agency's designation and certification of the administrative record as complete is entitled to a "presumption of administrative regularity." *McCrary v. Gutierrez*, 495 F. Supp. 2d 1038, 1041 (N.D. Cal. 2007) (citing *Bar MK Ranches v. Yuetter*, 994 F.2d 735, 740 (10th Cir. 1993)). In turn, courts presume administrative records are complete, but plaintiffs can rebut this presumption with "clear evidence to the contrary." *In re United States*, 875 F.3d 1200, 1206 (9th Cir. 2017) (citing *Bar MK Ranches*, 994 F.2d at 740), *vacated on other grounds*, 138 S. Ct. 443 (2017)).

A court generally may not consider extra-record evidence, although the Ninth Circuit has recognized certain exceptions to that rule. *San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 992 (9th Cir. 2014). These exceptions are when admission of the evidence: "(1) is necessary to determine whether the agency has considered all relevant factors and has explained its decision, (2) is necessary to determine whether the agency has relied on documents not in the record, (3) [] is necessary to explain technical terms or complex subject matter, or (4) when plaintiffs make a showing of agency bad faith." *Id.* (citations and quotations omitted). The exceptions are to be "narrowly construed," and the party seeking to supplement with the extra-record evidence "bears the burden of demonstrating that a relevant exception applies." *Id.* at 992–93. Otherwise, "[w]ere the federal courts routinely or liberally to admit new evidence when reviewing agency decisions, it would be obvious that the federal courts would be proceeding, in effect, de novo rather than with the proper deference to agency processes, expertise, and decision-making." *Lands Council v. Powell*, 395 F.3d 1019, 1030 (9th Cir. 2005).

B. Discussion

Plaintiff has not presented any "clear evidence" to overcome the applicable presumption of deference to the agency's judgment that the AR is complete. *See In re United States*, 875 F.3d at

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1206. Nor has Plaintiff demonstrated that any of the narrow exceptions to supplement the AR apply in this case. See San Luis, 776 F.3d at 992. Plaintiff, in conclusory fashion, argues that "clearly' the MAC could not have obtained information about the off-label uses of Serostim for HIV" without considering the AHFS-DI compendium. Dkt. No. 79 at 3. As to the introductory portion, according to Plaintiff, it is "preposterous to assume that the decision-makers in this case never relied on something so clearly foundational." Id. Plaintiff then asserts that DHHS's objection to providing the documents "is evidence of concealment," and that DHHS propounds an "absurd and condescending reason" for failing to provide the documents. *Id.* at 3, 5.

Plaintiff completely misses the mark. These conclusory pronouncements come nowhere close to showing "clear evidence" that any of the documents should be in the AR. The record reflects that the agency considered DRUGDEX, another Medicare-approved compendium, to determine what the non FDA-approved (or "off-label") use for Serostim is. AR at 0055, 0726. Plaintiff does not dispute that DRUGDEX is in the administrative record. Dkt. No. 70 at 5 n.3. The ALJs, in their opinions, also stated that the AHFS-DI compendium did not include any additional off-label uses for Serostim. AR at 0055, 0726. The record does not reflect any reference to "somatotropin," and Plaintiff presents no evidence that the agency relied on information about this drug. Plaintiff does not present any evidence, let alone "clear evidence," that the agency considered any of the materials whose inclusion he seeks to compel.

Because Plaintiff fails to rebut with clear evidence the presumption that the administrative record is complete, or present any evidence that the documents fall under one of the exceptions allowing the Court to consider extra-record evidence, the Court **DENIES** Plaintiff's second motion to supplement the administrative record.

IV. MOTION TO FILE UNDER SEAL

DHHS filed the entire certified administrative record, approximately 1,500 pages, with the Court, along with a motion requesting to file the record under seal. Dkt. No. 64. Because these records are more than tangentially related to the underlying action, the Court applies the "compelling reasons" standard articulated below.

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A. Legal Standard

Courts generally apply a "compelling reasons" standard when considering motions to seal documents. Pintos v. Pac. Creditors Ass'n, 605 F.3d 665, 678 (9th Cir. 2010) (quoting Kamakana v. City & Cty. of Honolulu, 447 F.3d 1172, 1178 (9th Cir. 2006)). "This standard derives from the common law right 'to inspect and copy public records and documents, including judicial records and documents." Id. (quoting Kamakana, 447 F.3d at 1178). "[A] strong presumption in favor of access is the starting point." Kamakana, 447 F.3d at 1178 (quotations omitted). To overcome this strong presumption, the party seeking to seal a judicial record attached to a dispositive motion must "articulate compelling reasons supported by specific factual findings that outweigh the general history of access and the public policies favoring disclosure, such as the public interest in understanding the judicial process" and "significant public events." *Id.* at 1178–79 (quotations omitted). "In general, 'compelling reasons' sufficient to outweigh the public's interest in disclosure and justify sealing court records exist when such 'court files might have become a vehicle for improper purposes,' such as the use of records to gratify private spite, promote public scandal, circulate libelous statements, or release trade secrets." Id. at 1179 (quoting Nixon v. Warner Commc'ns, Inc., 435 U.S. 589, 598 (1978)). "The mere fact that the production of records may lead to a litigant's embarrassment, incrimination, or exposure to further litigation will not, without more, compel the court to seal its records." Id.

The Court must "balance[] the competing interests of the public and the party who seeks to keep certain judicial records secret. After considering these interests, if the court decides to seal certain judicial records, it must base its decision on a compelling reason and articulate the factual basis for its ruling, without relying on hypothesis or conjecture." *Id.* Civil Local Rule 79-5 supplements the compelling reasons standard set forth in *Kamakana*: the party seeking to file a document or portions of it under seal must "establish[] that the document, or portions thereof, are privileged, protectable as a trade secret or otherwise entitled to protection under the law . . . The request must be narrowly tailored to seek sealing only of sealable material." Civil L.R. 79-5(b).

B. Discussion

The Court finds that DHHS has shown a compelling interest in sealing the entire

administrative record, as it contains Plaintiff's medical records and private information. Courts have found a party's privacy interests in such records to outweigh the public's interest in access. *See A.B. v. San Francisco Unified Sch. Dist.*, No. C 07-4738 PJH, 2007 WL 2900527, at *1 (N.D. Cal. Oct. 2, 2007) (granting motion to seal administrative record "which often contains sensitive educational and medical information, and often in references too numerous to redact"); *see also Krysten v. Blue Shield of California*, No. 15-CV-02421-RS, 2016 WL 5934709, at *3 n.3 (N.D. Cal. Oct. 11, 2016); *A.C. v. City of Santa Clara*, No. 13-CV-03276-HSG, 2015 WL 4076364, at *2 (N.D. Cal. July 2, 2015).

V. CONCLUSION

The Court **GRANTS** all three motions to dismiss without leave to amend. Dkt. Nos. 36, 39, 40. The clerk is **DIRECTED** to terminate Defendants Envision and Blue Shield from the case. The Court also **DENIES AS MOOT** Plaintiff's first motion to supplement the administrative record, Dkt. No. 24; **DENIES** Plaintiff's second motion to supplement the administrative record, Dkt. No. 70; and **GRANTS** Defendant's motion to file the administrative record under seal, Dkt. No. 64.

The Court further **SETS** a case management conference for July 23, 2019 at 2:00 p.m., and **DIRECTS** the parties to file on or before July 16, 2019 a joint case management statement including a proposed case schedule for resolution of the remaining claim against DHHS.

IT IS SO ORDERED.

Dated: 6/18/2019

HAYWOOD S. GILLIAM, JR. United States District Judge